

Oversight and Investigations Subcommittee
“The Heparin Disaster: Chinese Counterfeits and American Failures”
April 29, 2008

Johanna Staples Statement

I want to sincerely thank this committee for providing us this opportunity to speak and share the stories of our loss. It is a remarkable thing that you are doing for our families and we appreciate it beyond words. In this land of freedom we have come to expect that we are protected and safe. It is an overwhelming experience for us to find out that there are circumstances that are beyond our control – circumstances from which we are not safe. We might think we are protected from harm and catastrophe, but it is an empty and false sense of security. End Stage Renal patients must be connected to a machine and submit to recurrent dialysis treatments. Each treatment lasts 4 or more hours while the patient’s blood is systematically removed from their body and toxins are carefully cleared from their blood as it flows through the dialysis machine and then returned. This process is repeated usually three times per week and more for patients like my husband. In this process many life-saving drugs are used due to renal failure, drugs that are essential to this treatment. Patients need to know the drugs that they must use are reliable and secure. That’s what I thought. Patients can remain on dialysis for an unlimited period of time. Actually they can remain on dialysis for many years. Transplantation is the ideal decision for someone with this disease, but my husband always felt that someone else should have the kidney and opportunity and he discarded the idea of receiving a transplant.

I so want this statement to be that truly poignant and touching piece that really makes you think about the man of whom I speak. I want it to be a statement that honestly reveals all the reasons why we are all so devastated by the loss of Dennis Staples. I know I have the passion and the motivation to tell you of our loss but I fear I don't have adequate skills to speak eloquently and give you a true sense that really shares with you all of the facets of the complex man that I can no longer see, hear, touch or smell. I loved my husband with all my heart and dearly miss him every minute of every day with an ache that cannot be dulled or cured. Even if he was taken from us a single day too soon that day was still priceless to us and we can never get it back. Dennis lapsed into coma the day before he was to turn 60 years old. We lost Dennis -- but he lost us too. He lost his life, his birthday, his party and his chance to visit one last time with his loved ones and his friends nestled around him to celebrate with him.

Dennis Staples was important. He was important because he was my husband of nearly 32 years. He was my confidant, my sounding board, my companion, my partner, my editor, my business partner, my financial advisor, my pride, my past, my present, my life, and my heart. He was important as a father and new grandfather. He was important to his brothers, his nieces, nephews, and to his brothers and sisters-in-law. He was important to his friends, his family, his acquaintances and his public. He was an entertainer, and well-known radio announcer in Toledo for over 20 years. He had many listeners who have reported and continue to report that they miss him dearly. He was important in the community in which he lived but he was also important to his family. He, much to his dismay, was an icon in the community that he so loved. He accepted the hand that was dealt him regarding his health without contempt or malice.

He accepted his disease without anger and was resolved to do the best he could with whatever came his way.

Dennis Staples was a man who possessed incredible integrity. He was a man who had an amazing intellect and an extensive vocabulary. He had a quick wit and an equally remarkable capacity for love. He loved everything about life; politics, music, trivia, learning, cooking, performing, acting, reading and writing. He loved his family and friends and he loved life. He was a humble man who lived in a body that was old before its time. He had a heart of gold and would share whatever he had to help out someone in need. In conversations he gave you unconditional attention and had a way of making you feel like he couldn't wait to hear what you would say next.

On the last day of my husband's conscious life he had a truly splendid morning. He was in a superb mood, busy planning a special dinner at a favorite local steak house with one of our beloved doctors and his wife. Dennis was actively thinking about last minute preparations for his first-ever birthday party and he was so amazed that he would actually be able to celebrate the 60th anniversary of his birth. When we awoke that last day, he carefully laid out his proposal of the ideal plans for the day so that we would have the same game plan before I left for work to teach my disabled kindergarten students.

As I left the house for work Dennis said, "You go to school, and I'll go to dialysis and when we both get home, you can get me bathed and change my dressings, and I will relax while you get ready." He was looking forward to dinner out so much that he barely spoke of anything that wasn't related to dinner, his birthday and his party. This dinner would be our chance to spend quality time with a truly caring doctor that we

had really good reasons to trust. This is a physician for whom we hold the greatest respect and he is a man to whom we owe so many thanks for repeatedly going above and beyond the call of duty on our behalf.

On our medical journey there have been a multitude of doctors and we have had the distinct pleasure of being connected with some of the very best. This is important because disease takes a horrific toll on its victims. That toll is key to the sheer number of doctors that must be involved in the life of a diabetic. To begin, there are complications with digestion, heart, eyes, lungs, kidneys, other organs and limbs. There are Critical Care, Primary Care and Infectious Disease Physicians; Cardiologists, Endocrinologists, Nephrologists, Neurologists, Ophthalmologists, Radiologists, Urologists, plus Pulmonary and Retina Specialists, along with Cardiac, General, Neurosurgeons and Vascular Surgeons, and a host of other medical personnel who I haven't the time to name.

When our daughter Lexi picked up Dennis for his dialysis treatment that Wednesday, he was almost giddy with plans for the day. He was chatty and quick to share with her what he planned to do that evening. When they arrived at the treatment center, while Lexi was collecting and helping him into his wheelchair, they were approached by a firefighter who asked, "Do you need help?" My husband responded with a short and sweet answer, "No, thanks." Followed by, "Well good, because I would hate to see my hero fall down." The firefighter went on to talk to Dennis about how he had had a genuine impact upon his life when the young fireman to be was an intern at the radio station where my husband had worked with his partner, Bob Kelly. This young

community helper praised Dennis again and offered him further assistance if he were ever to need it.

In the weeks leading up to his death, Dennis was made to suffer many indignities without complaint. He was no stranger to dreadful experiences. He worked hard to maintain his health and yet he still had to deal with losing his ability to walk and drive. This formerly independent man was forced to rely on the assistance of others to move about and to care for all of his personal needs. He needed others to help bathe and clothe him. He needed us to do his dressing changes. He needed assistance with every facet of his daily life – assistance for just about everything he did, for transportation, mobility, and for all his ongoing treatments.

Dennis would have worked far longer if his health hadn't interfered with his life plans. Twenty-eight months before he died, Dennis had to go on dialysis because his kidneys failed. Sixteen months before he died, he retired from his job because he could no longer reliably go to work. Yet, he was able to rebound and move on from all these things. But he could not survive the contaminated heparin.

There were many people who paid their respects at the funeral home. There were many people that I had never met. There were people who he helped when he worked as a counselor at a local hospital. There were people who listened to his daily radio program and missed hearing his voice. There were local politicians and well-known entertainers, local celebrities and personalities from all types of media. We even received proclamations from both our mayor and the city council on my husband's behalf. In our local newspaper his passing was actually given celebrity obituary status. As my husband often marveled, he really felt that he had become a big fish in our little

local pond. He would have been so touched to see the outpouring of grief from our community at his death – and that death was far too soon. Over the years, Dennis had made a multitude of local commercials for both radio and television and accordingly I am often reluctant to watch and/or listen to local stations for fear that I might be surprised and startled to hear his voice when I least expect it.

The last day of Dennis' conscious life he went to dialysis as usual. Treatment was delayed because his permanent catheter was not functioning and blood could not be pulled from nor returned to his body. He needed his dialysis. His nurse gave him a drug called Activase in an attempt to help his blood flow. This procedure was deemed successful so he was given a bolus of Heparin and his treatment resumed. Shortly after Dennis began dialysis for the second time, he suffered an event. My husband became unresponsive and he stopped breathing causing cardiac arrest. His caregiver was speaking to him at the time of the event and CPR was immediately administered. Medical procedure was followed and 911 called, with paramedics arriving in only three minutes, since their station was located across the street and visible from the front of the center. Emergency personnel began life-saving measures. I arrived at the dialysis center in time to be transported by ambulance along with my husband in record time, to the hospital emergency room. This hospital was less than 5 minutes away from the treatment center where he arrested. Upon arrival at the emergency room, Dennis received immediate attention by a waiting ER staff. Dennis survived the event but without neurological recovery. He never again regained consciousness in spite of everyone's efforts, and the speedy initiation of medical treatment. Professionals were unable to save his life.

I worked hard to celebrate my husband's life and make my peace with his loss. I thought I was well on my way to learning how to deal with his passing – and then I found out about the contaminated Heparin. As people were permitted to suffer and die from this crop of tainted drugs, in 2007 Baxter Pharmaceuticals CEO Robert L. Parkinson, Jr., was paid, in total compensation, \$17.6 million dollars, nearly 1.5 million dollars a month.

Baxter's global net sales totaled 11.3 billion in 2007, which at an increase of 9% from 2006. Sales in the United States alone totaled over \$4.8 billion, an increase of 5% over the prior year. International sales totaled over \$6.4 billion, increasing 11% compared to the prior year. Baxter reinstated quarterly scheduled payments of dividends in 2007, and increased the annual 2007 dividend rate by 15 percent. Heparin, a drug that could have been recalled sooner made untold profits. It was made more economically with ingredients that could be produced less expensively in China. Baxter paid an increase of \$340 million in cash dividends to shareholders and total dividends for 2007 were over \$700 million.

In late 2007, Baxter's board of directors reevaluated stockholder dividends based on company profitability and they declared a quarterly dividend that represented a 30% increase over the previous quarterly rate. Company profitability surely increased for 2007 -- but at what cost? Baxter supplied tainted Heparin for use in medical facilities to patients who were in need. This drug surely helped to increase Baxter's corporate bottom line. Baxter provided greater dividends to stockholders plus additional benefits to board members, while the corporation failed to recall a bad drug; a drug that was

already known to have adverse effects -- so my husband and many other ailing patients who received the drug suffered needlessly... Dennis and others died.

I just don't blame Baxter and their drive for profits. I also blame the FDA for not doing its job to insure that the drugs sold in this country are safe.

In conclusion, I want to thank the hard working doctors and scientists who have worked to unravel this tale of deception. While Baxter and the FDA failed, the scientists and doctors who recently published their findings in the *New England Journal of Medicine*¹ have done their job, and done it well. They have proven that the sudden drops in blood pressure and the other symptoms which my husband and others suffered from before their death were caused by the contamination.

Finally I want to thank this Committee, in advance, for doing its job and passing the laws that are needed to secure a safe drug supply for my fellow citizens.

Respectfully Submitted,

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¹ Contaminated Heparin Associated with Adverse Clinical Events and Activation of the Contact System, Kishimoto, *et al*, *new England Journal of Med* 2008;358, published at www.nejm.org on April 23, 2008.